Quidel Corporation

QuickVue® One-Step hCG Combo
Procedure Manual

Procedure:

Prepared by	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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This Procedural Bulletin is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete package insert. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete package insert in accordance with FDA labeling regulation (21CFR809.10). Prepared in accordance with the guidelines recommended by the National Committee for Clinical Laboratory Standards, Villanova, PA 19085; NCCLS Document GP2-A2.

QuickVue® One-Step hCG Combo
Procedure Manual

PRINCIPLE:

The QuickVue One-Step hCG-Combo Test is a sensitive immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine for the early detection of pregnancy.

Human chorionic gonadotropin is a hormone produced by the placenta shortly after implantation. Since hCG is present in the serum and urine of pregnant women, it is an excellent marker for confirming pregnancy.

The QuickVue test uses a monoclonal antibody specific to the beta subunit of hCG in a single-step technology to accurately detect hCG.

Serum or urine is added to the Sample Well on the Test Cassette. If hCG is present in the specimen at a level of 10mIU/mL with serum samples or 20 mIU/mL with urine samples, a pink-to-purple Test (T) Line will appear along with a blue Procedural Control (C) Line in the Result Window. If hCG is present at very low levels, or not present in the specimen, only a blue Procedural Control Line will appear in the Result Window.

SPECIMEN:

Serum

No special patient preparation is necessary. A whole blood specimen should be obtained by standard medical procedures. After clotting has occurred, the separated serum should be used for testing.

Serum specimens may be stored refrigerated 36-46 °F (2–8°C) for up to 48 hours prior to assay. If testing will be delayed for more than 48 hours, the sample may be frozen once at –20°C or below. If frozen, mix after thawing. Do not re-freeze. Do not chemically modify the serum in any way.

Urine

Collect specimens in clean containers. First morning specimens generally contain the highest concentrations of hCG and are recommended for early detection of pregnancy. However, any urine sample is suitable for testing.

Urine specimens may be kept at room temperature for up to 8 hours or stored refrigerated at 36-46 °F (2–8°C) for up to 3 days. Do not freeze specimens.

EQUIPMENT AND MATERIALS:

Reagents and Materials Supplied

• 25 or 75 individually wrapped Test Cassettes
-Each cassette contains murine monoclonal antibody and caprine polyclonal antibody to hCG

• 25 or 75 disposable pipets
• 1 Package Insert

Materials Required but not Provided

• Watch or clock that measures minutes
• Specimen collection containers

Materials Recommended but not Provided

• External hCG controls traceable to WHO Standard (3rd IS 75/537).

WARNINGS AND PRECAUTIONS:

• Kit contents are for *in vitro* diagnostic use.
• Do not use kit contents after the expiration date printed on the outside of the kit.
• Use appropriate precautions in the collection, handling, storage and disposal of the specimens and used kit contents [1]. Discard used pipets and test cassettes in a proper biohazard container.
• To obtain accurate results, you must follow the Package Insert instructions.

KIT STORAGE AND STABILITY:

Store kit at room temperature 59–86°F (15–30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box carton. Do not freeze.

QUALITY CONTROL:

Built-in Quality Control Features

The QuickVue test contains built-in control features. The development of the blue Procedural Control Line next to the letter "C" is a positive procedural control. If this line does not develop, the test result is invalid. The absence of interfering background is a negative procedural control. If background color appears in the Result Window which interferes with your ability to read the test result, your result may be invalid. In this case, contact QUIDEL Technical Assistance.

Optional Quality Control Feature

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Good laboratory practice recommends the use of external controls to assure that the reagents and assay are performing properly. For this purpose, we recommend the QuickVue hCG Controls (QUIDEL Catalog Number 0272), or the hCG Serum Control Set (QUIDEL Catalog Number 0281). External Controls should be tested with each new lot or shipment of test materials once for each 25-test kit, and as otherwise required by your laboratory's standard quality control procedures.

1. External Positive Control: Process the control as you would a patient sample. A positive signal is indicated by the appearance of a pink-to-purple Test Line, along with a blue procedural Control Line.

2. External Negative Control: Process the control as you would a patient specimen. A negative signal is indicated by the appearance of the blue procedural Control Line only.

TEST PROCEDURE:

Set up a sufficient number of appropriately labeled Test Cassettes.
Use a new disposable pipet for each specimen.

- Remove the QuickVue Test Cassette from the foil pouch and place it on a clean, dry, level surface.
- Using one of the disposable pipets supplied, add **3 DROPS (125 uL)** of serum or urine to the **Round Sample Well** on the Test Cassette. The Test Cassette should not be moved again until the assay is complete and ready for interpretation.

• **FOR URINE**: Read result at **3 minutes**.

• **FOR SERUM**: Read result at **5 minutes**.

• **Note:** Some positive results may be seen earlier.

INTERPRETATION:

See Procedure Card for color result interpretation.

Positive:

The appearance of **any pink-to-purple line** next to the letter "T" in the Result Window, along with a blue Procedural Control Line next to the letter "C".

Negative:

The appearance of the blue Procedural Control Line next to the letter "C" only and no pink-to-purple Test Line next to the letter "T" at 3 minutes for urine or at 5 minutes for serum.

No Result:

If no blue Procedural Control Line appears, the test result is invalid and the specimen must be retested.

A specimen with a low level of hCG may show color development over time. If a negative result is obtained but pregnancy is suspected, another specimen should be collected after 48–72 hours and tested.

LIMITATIONS OF THE PROCEDURE:

- The contents of this kit are for use in the **qualitative** detection of hCG in serum or urine.

- Test results must always be evaluated with other data available to the physician.

- While pregnancy is the most likely reason for the presence of hCG in serum and urine, elevated hCG concentrations unrelated to pregnancy have been reported in some patients[2,3]. Patients with trophoblastic and nontrophoblastic disease may have elevated hCG levels, therefore, the possibility of hCG secreting neoplasms should be eliminated prior to the diagnosis of pregnancy[8] .

- hCG may remain detectable for a few days to several weeks after delivery, spontaneous abortion, or hCG injections[4] .

- Very low levels of hCG are present in serum and in urine shortly after implantation. Positive test results from very early pregnancy may later prove negative due to natural termination of pregnancy. This is estimated to occur in 31% of pregnancies overall and 22% of clinically unrecognized pregnancies[5] . If a very low, faint positive serum result is obtained, another sample should be obtained in 48 hours and retested. If waiting 48 hours is not medically advisable, the test result should be confirmed with a quantitative hCG test.

- A normal pregnancy cannot be distinguished from ectopic pregnancy based on hCG levels alone. Abnormal pregnancies cannot be diagnosed by qualitative hCG results. The above conditions should be ruled out when diagnosing pregnancy.

- If a urine sample is too dilute, it may not contain a representative urinary hCG concentration. If a negative result is obtained and pregnancy is still suspected, a first morning sample should be obtained and tested.

EXPECTED VALUES:

Specimens containing as low as 10 mIU/mL (serum) or 20 mIU/mL (urine) (calibrated against the WHO 3rd IS 75/537) hCG will yield positive results when tested with the QuickVue Test. In normal pregnancy, hCG can be detected as early as 6 days following conception with concentrations doubling every 32 to 48 hours, peaking in excess of 100,000†mIU/mL inapproximately ten to twelve weeks. Levels of 25 mIU/mL are reportedly present in serum and urine as early as two to three days before expected menses[6] . Serum hCG is rapidly cleared into the urine and the concentration of hCG in serum is approximately equal to the concentration in urine[7].

PERFORMANCE CHARACTERISTICS:

The QuickVue test was used to assay 497 urine specimens and 1583 serum specimens from patients presenting for pregnancy testing. Positive and negative results were compared to results obtained with the Hybritech ICON® II hCG ImmunoConcentration Assay™ . A quantitative method was used to resolve any discrepant results.

Of the 497 urine specimens evaluated, 270 specimens tested positive and 227 specimens tested negative by both the QuickVue test and the comparative test methods. A concordance of >99% was determined for these specimens.

Similarly, of the 1583 serum specimens evaluated, 684 specimens tested positive and 899 specimens tested negative by both the QuickVue test and the comparative test. A concordance of >99% was determined for these specimens.

Urine Correlation

		ICON II hCG +	ICON II hCG −	
QuickVue hCG-Combo	+	270	0	Sensitivity: >99% Specificity: >99% Accuracy: >99%
	−	0	227	

Serum Correlation

		ICON II hCG +	ICON II hCG −	
QuickVue hCG-Combo	+	684	0	Sensitivity: >99% Specificity: >99% Accuracy: >99%
	−			

– 0 899

PHYSICIAN'S OFFICE LABORATORY (POL) STUDIES:

An evaluation of the QuickVue test was conducted at three Physicians' Offices using a panel of coded specimens. Testing was performed by physician's office personnel with diverse educational backgrounds and work experience at different locations. The proficiency panel contained negative, low positive, moderate positive and high positive specimens. Each specimen level was tested in replicates of five at each site over a period of three days.

The results obtained at each site had 100% agreement with the expected results. No significant differences were observed within run (five replicates), between runs (three different assay days), or between sites (POL sites).

CROSS-REACTIVITY:

hTSH, hLH, and hFSH were tested in the QuickVue test at levels ranging from 1000 μIU/mL to 1000 mIU/mL and did not affect the expected results.

INTERFERENCE TESTING:

The following chemical and biological compounds were tested using the QuickVue test and did not affect the expected results.

URINE ANALYTES	**CONCENTRATION**
Albumin (serum)	2000 mg/dL
Bilirubin	1000 μg/dL
Hemoglobin	1000 μg/dL
Glucose	2000 mg/dL
Urine pH	5-9

HORMONES	**CONCENTRATION**
hLH	300 mIU/mL
hFSH	1000 mIU/mL
hTSH	1000 μIU/mL

Estriol 17-beta	1400 µg/dL
Pregnanediol	1500 µg/dL

BACTERIA	**CONCENTRATION**
E. coli	10^8 CFU/mL
Group B Streptococcus	2.5×10^7 CFU/mL
Chlamydia trachomatis	10^7 IFU/mL

CHEMICAL ANALYTES	**CONCENTRATION**
Acetaminophen	20 mg/dL
Ascorbic Acid	20 mg/dL
Caffeine	20 mg/dL
Gentisic Acid	20 mg/dL
Salicylic Acid	20 mg/dL
EDTA	80 mg/dL
Cannabinol	10 mg/dL
Cocaine	10 mg/dL
Codeine	10 mg/dL
Heroin	1 mg/dL
Methadone	10 mg/dL
Methamphetamine	10 mg/dL

CHEMICAL ANALYTES	**CONCENTRATION**
Methanol	10.0%
Acetoacetic Acid	2000 mg/dL
β-Hydroxybutyrate	2000 mg/dL
Ephedrine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Phenothiazine	20 mg/dL
Acetylsalicyclic Acid	20 mg/dL
Benzoylecgonine (cocaine metabolite)	10 mg/dL
Ethanol	1.0 %
DMSO	5.0 %
Uric Acid	20 mg/dL
Heparin	2800 units/dL

COMMENTS AND TECHNICAL ASSISTANCE:

If you have any questions regarding the use of this product, please call QUIDEL's Technical Assistance toll-free number, (800) 874-1517, Monday through Friday, between 7:00 AM and 5:00 PM, Pacific Time. If outside of the United States, contact your local distributor.

REFERENCES:

1. *Recommendations for the Prevention of HIV Transmission in Health Care Settings*, Morbidity and Mortality Weekly Report, Centers for Disease Control, August 21, 1987.

2. Saxena, BB. *Endocrinology of Pregnancy*, 3rd. ed. F. Fuchs, A Klopper, Eds., Harper and Row, Philadelphia, PA, 1983; 50-72.

3. Krieg AF, In *Clinical Diagnosis and Management by Laboratory Methods*, Vol. 1, 16th ed., JB Henry, Ed., W.B. Saunders Co., Philadelphia, 1979, 680-692.

4. Steier JA, Bergsjo P, Myking OL. *Obstet Gynecol* 64: 391-394, (1984).

5. Wilcox AJ, Weinberg CR, O'Connor JF, Baird DD, Schlatterer JP, Canfleld RE, Armstrong EG, Nisula BC. Incidence of Early Loss of Pregnancy, *N Eng J Med* 319: 189-194, (1988).

6. Braunstein GD, Rasor J, Adler D, Danzer H, Wade ME. *American Journal of Obstetrics and Gynecology* 126, 1976; 678-681, (1976).

7. McCready J, Braunstein GD, Helm D, Wade ME. *Clin Chem* 24: 1958-1961, (1978).

8. Lenton, E.A., Newal, L.M., and Sulaiman, R., *Fertility and Sterility* 37: 773-778, (1982).

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Log Sheet QuickVue® One-Step hCG Combo Lot Number _____
Exp. Date _____

Record Built-in Positive and Negative Controls on the first patient tested each day.

	Date	Patient Name	Positive Procedural Control (C=Blue Line)	Negative Procedural Control (Background=no interference)	Test Result at 3 (urine) or 5 (serum) minutes	Tech.
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						